V. 510(k) Summary

APR - 9 2003

Submitter
MedAmicus, Incorporated
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Date Prepared
March 20, 2003

Trade Name
MedAmicus FlowGuard™ Peelable Introducer

Common Name
Catheter Introducer

Predicate Device
MedAmicus Valved Peelable Introducer K021004

Device Description

The MedAmicus FlowGuard™ Peelable Introducer is a small diameter tubular shaped device with integrated proximal handles. The FlowGuard™ Peelable Introducer is designed to provide a relatively atraumatic method for implanting catheters and pacemaker leads into the venous system. The FlowGuard™ Peelable Introducer has a "tear-away" feature common to the predicate devices. This feature allows the user to remove the introducer without removing the inserted catheter or pacing lead. The MedAmicus FlowGuard™ Peelable Introducer is packaged in three configurations: 1) a convenience kit containing a MedAmicus FlowGuard™ Peelable Introducer, a thin-wall needle, a disposable syringe, and a flexible guidewire, packaged in a tray and a sealed pouch. 2) individually pouched, sterile MedAmicus FlowGuard™ Peelable Introducer and 3) bulk, nonsterile MedAmicus FlowGuard™ Peelable Introducers.

Intended Use

There are no changes to the Intended Use of the device from the currently approved device.

> *The MedAmics FlowGuard™ Peelable Introducer is indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.*

Technological Characteristics

The modified packaging of this device is technologically equivalent to the currently approved device.

Summary of Studies

Design Verification of the device is not required as there are no design modifications to the device. A packaging validation will be completed for the individually pouched, sterile introducers to ensure that there is no effect on the safety and effectiveness of the device. This validation will be completed based on a Risk Analysis per internal procedures that are compliant with European Standard EN1441: 1998 Medical Devices – Risk Analysis. This Risk Analysis was completed by comparing the risks associated with the new packaging configurations with the currently approved convenience kit packaging. This validation is summarized in Section X of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2003

Mr. Karyl Haskell
Quality Assuarance and Regulatory Affairs Manager
MedAmicus, Incorporated
15301 Highway 55 West
Minneapolis, MN 55447

Re: K030905
Trade/Device Name: MedAmicus FlowGuard™ Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II
Product Code: DYB
Dated: March 21, 2003
Received: March 24, 2003

Dear Mr. Haskell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

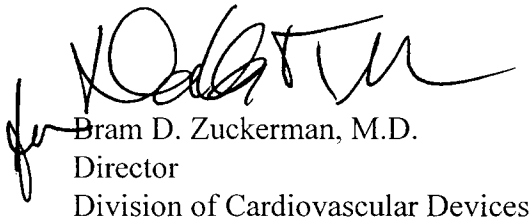
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. Indications for Use

510(k) Number (if known): Not Assigned K030905

Device Name: MedAmicus FlowGuard™ Peelable Introducer

Indications for Use: The MedAmicus FlowGuard™ Peelable Introducer indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030905